

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
OFFORD, Robin E. et al.

Appl. No. **To Be Assigned**

Filed: **Herewith**

For: **Polypeptide and Protein
Derivatives and Process for Their
Preparation**

Art Unit: **To be Determined**

Examiner: **To be Determined**

Atty. Docket: **03504-115-CON**

**Information Disclosure Statement
Pursuant to 37 C.F.R. § 1.97(b)(1)**

Honorable Commissioner of Patents
PO Box 1450
Alexandria VA 22313-1450

Dear Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents may be found in the file histories of Applicants' parent applications:

U.S. Patent Application Serial No. 08/241,687, filed May 12, 1994;
U.S. Patent Application Serial No. 08/089,051, filed August 6, 1993;
U.S. Patent Application Serial No. 07/866,262, filed April 10, 1992;
U.S. Patent Application Serial No. 07/742,159, filed August 1, 1991;
U.S. Patent Application Serial No. 07/506,545, filed April 5, 1990;
U.S. Patent Application Serial No. 07/380,738, filed July 17, 1989;
U.S. Patent Application Serial No. 07/220,196, filed July 18, 1988; and
U.S. Patent Application Serial No. 07/043,530, filed on April 28, 1987.

The Examiner is requested to contact an undersigned immediately in the event that any cited document may be unavailable, in order that a replacement copy can be provided.

This Information Disclosure Statements is being submitted prior to an Initial Office Action. No fee is accordingly believed due for consideration of this Information Disclosure Statement. However, if the Commissioner determines that an additional fee is required in for consideration of this Information Disclosure Statement, the U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to Deposit Account No. 50-0548 referencing docket number 3504.115-CON.

The submitted documents are:

| | | |
|-----|---------------------------|-----------------|
| AA1 | U.S. Patent No. 4,691,006 | Stevens |
| AB1 | U.S. Patent No. 4,699,784 | Shih et al. |
| AC1 | U.S. Patent No. 3,903,069 | Gregory et al. |
| AD1 | U.S. Patent No. 4,707,352 | Stavrianopoulos |
| AE1 | U.S. Patent No. 4,352,751 | Wieder et al. |
| AF1 | U.S. Patent No. 3,856,771 | Jackson |
| AA2 | U.S. Patent No. 3,864,325 | Smyth |
| AB2 | U.S. Patent No. 4,029,642 | Obermeier |
| AC2 | U.S. Patent No. 4,183,849 | Hansen et al. |
| AD2 | U.S. Patent No. 5,045,451 | Uhr et al. |
| AE2 | U.S. Patent No. 5,106,951 | Morgan et al. |
| AF2 | U.S. Patent No. 4,722,899 | Hamaoka et al. |

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| AL1 | EP 0 088 695 |
| AM1 | EP 0 243 929 |
| AN1 | JP 2528464 |
| AL2 | JP 3525/72 |
| AM2 | WO 90/02136 |
| AR1 | Bayer, E.A. et al., "The Avidin-Biotin Complex in Affinity Cytochemistry," Methods in Enzymology 62: 308 (1979) |
| AS1 | Brady et al., Selective Decrease in T Relaxation Times," abstract, Magnetic Resonance in Medicine 1: 286 (1984) |
| AT1 | Canova-Davis, E. et al., "Semisynthesis of insulin: specific activation of the arginine carboxyl group of the B chain of desoctapeptide-(B23--30)-insulin (bovine)," Biochemistry 20: 7053 (1981) |
| AR2 | Chua, M.M. et al., "Attachment of immunoglobulin to Liposomal Membrane Via Protein Carbohydrate," Biochim. Biophys. Acta 800: 291 (1984) |
| AS2 | Dixon et al., "Specific Modification of NH ₂ – Terminal Residues by Transamination," Methods in Enzymology 25: 409 (1979) |
| AT2 | Fields et al., "A Spectrophotometric Method for the Microdetermination of Periodate," Biochem J. 108: 883 (1968) |
| AR3 | Friedman et al., "Reductive Alkylation of Proteins With Aromatic Aldehydes and Sodium Cyanoborohydride," Int. J. Peptide Protein Res. 6: 183 (1974) |
| AS3 | Gray, "The Direct Coupling of Oligosaccharides to Proteins and Derivatized Gels," Gels, Arch. Biochem. Biophys. 163: 426 (1974) |
| AT3 | Hansske et al., "Modification of the 3 Terminus by Periodate Oxidation," Methods in Enzymology LIX: 172 (1979) |

AR4 Heitzmann et al., Use of the Avidin-Biotin Complex for Specific Staining of Biological Membranes..., Proc. Natl. Acad. Sci. USA 71: 3537 (1974)

AS4 Hermentin et al., "Investigations with monoclonal antibody drug (anthracycline) conjugates," Behring Inst. Mitt No. 82 P. 197-215 (1988)

AT4 Hnatowich et al., "Radioactive Labeling of Antibody: A Simple And Efficient Method," Science 220: 613 (1983)

AR5 Hofmann et al., "Avidin Binding of Carboxyl-Substituted Biotin and Analogues," Biochemistry 21: 978 (1982)

AS5 Itaya et al., "Cell Surface Labeling of Erythrocyte Glycoproteins...", Biochem. Biophys. Res. Commun. 64: 1028 (1975)

AT5 Jentoft et al., "Protein Labeling by Reductive Alkylation," Methods in Enzymology 91: 570 (1983)

AR6 Ji, "Bifunctional Reagents," Methods in Enzymology 91: 580 (1983)

AS6 Jones et al., "The Proteinase-Catalysed Synthesis of Peptide Hydrazides," Biochem. J 203: 125 (1982)

AT6 King et al., "Preparation of Protein Conjugates Via Intermolecular Hydrazine Linkage," Biochemistry 25: 5774 (1986)

AR7 Kraehenbuhl et al., "Preparation and Characterization of an Immuno-Electron Microscope Tracer," J. Exp. Med. 139: 208 (1974)

AS7 Krejcarek et al., "Covalent Attachment of Chelating Groups to Macromolecules," Biochem. Biophys. Res. Commun. 77: 581 (1977)

AT7 Leibiger et al., "Structural Characterization of the Oligosaccharides of a Human Monoclonal Anti-Lipopolysaccharide Immunoglobulin M," Glycobiology p. 497-507 (1998)

AR8 Mach et al., "Tumor Localization in Patients by Radiolabeled Monoclonal Antibodies," Cancer Res. 43: 5593 (1983)

AS8 Mikolajczyk et al. "High Yield, Site-Specific Coupling of N-Terminally Modified s-Lactamase to a Proteolytically Derived Single-Sulfhydryl," Bioconjugate Chem. Vol. 5 No. 6

AT8 Murayama et al., "Modification of Immunoglobulin G Using Specific Reactivity of Sugar Moiety," *Immunochem.* 15: 523 (1978)

AR9 Quash et al., "The Preparation of Latex Particles with Covalently Bound Polyamines," *J. Immunol. Methods* 22: 165 (1978)

AS9 Rodwell et al., "Site-Specific Covalent Modification of Monoclonal Antibodies," *Proc. Natl. Acad. Sci. USA* 83: 2632 (1986)

AT9 Seaver, *Genetic Engineering News* p. 10 and 21 (1994)

AR10 Wagner et al., "Gallium-68 Labeling of Albumin and Albumin Microspheres," *J Nucl Med* p. 428-433 (1979)

AS10 Waldmann, "Monoclonal antibodies in diagnosis and therapy," *Science* 252:1657-1661 (1991)

AT10 Werlen, et al., "Site-Specific Immunoconjugates," *Tumor Targeting* p. 251-258 (1995)

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

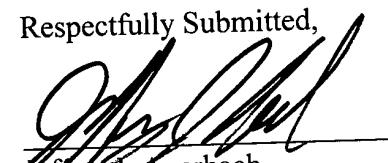
Applicant respectfully requests that the documents listed on the accompanying Form PTO 1449 be considered and made of record in the present application.

Applicant further requests that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

While the listed references are considered relevant to the prosecution of the present application, it is submitted that the references, either alone or in combination, do not detract from the patentability of the claimed invention.

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Respectfully Submitted,



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Registration No. 32,680
Attorney for Applicant

INFORMATION DISCLOSURE STATEMENT

Atty Dkt: 03504-115-CON

Serial No. To be Assigned

Title: **Polypeptide and Protein Derivatives and Process for Their Preparation**Applicant: **OFFORD, Robin E. et al.**Filing Date:
HerewithGroup:
To be Assigned**U.S. PATENT DOCUMENTS**

| Examiner's Initial | | Patent Number | Date (mm/dd/yyyy) | Name | Class | Sub-Class | Filing Date (mm/dd/yyyy) |
|--------------------|--|---------------|-------------------|-----------------|-------|-----------|--------------------------|
| AA1 | | 4,691,006 | 09/01/1987 | Stevens | 530 | 324 | 11/02/1984 |
| AB1 | | 4,699,784 | 10/13/1987 | Shih et al. | 424 | 181.1 | 02/25/1986 |
| AC1 | | 3,903,069 | 09/02/1975 | Gregory et al. | 260 | 112.7 | 11/30/1973 |
| AD1 | | 4,707,352 | 11/17/1987 | Stavrianopoulos | 424 | 1.17 | 01/30/1984 |
| AE1 | | 4,352,751 | 10/05/1982 | Wieder et al. | 530 | 303 | 09/10/1979 |

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| AL1 | | EP 0 088 695 | 9/1983 | Europe | G01N | 33/53 | No |
| AM1 | | EP 0 243 929 | 9/1995 | Europe | C07K | 14/00 | No |
| AN1 | | JP 2528464 | 6/1996 | Japan | C07K | 14/00 | No |

OTHERS, including Author, Title, Date, Pertinent Pages, etc.

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| AR1 | Bayer, E.A. et al., "The Avidin-Biotin Complex in Affinity Cytochemistry," Methods in Enzymology 62: 308 (1979) |
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| | AA2 | 3,864,325 | 02/04/1975 | Smyth | 260 | 112.7 | 11/13/1972 |
| | AB2 | 4,029,642 | 06/14/1977 | Obermeier | 530 | 303 | 12/19/1975 |
| | AC2 | 4,183,849 | 01/15/1980 | Hansen et al. | 530 | 305 | 12/08/1977 |
| | AD2 | 5,045,451 | 09/03/1991 | Uhr et al. | 435 | 7.23 | 10/26/1988 |
| | AE2 | 5,106,951 | 04/21/1992 | Morgan et al. | 530 | 391.9 | 03/31/1989 |
| | AF2 | 4,722,899 | 02/02/1988 | Hamaoka et al. | 435 | 70.21 | 06/20/1983 |

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| | AL2 | JP 3525/72 | 2/1972 | Japan | G01R | 31/26 | No |
| | AM2 | WO 90/02136 | 3/1990 | PCT | C07K | 3/08 | No |

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| | AR5 | Hofmann et al., "Avidin Binding of Carboxyl-Substituted Biotin and Analogues," Biochemistry 21: 978 (1982) |
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| | AA3 | | | | | | |
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| | AF3 | | | | | | |

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| | AR10 | Wagner et al., "Gallium-68 Labeling of Albumin and Albumin Microspheres," J Nucl Med p. 428-433 (1979) |
| | AS10 | Waldmann, "Monoclonal antibodies in diagnosis and therapy," Science 252:1657-1661 (1991) |
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